Serv Medical Pte. Ltd
Jing Zhang
Coo
3 Fraser Street, #04-23A Duo Tower
Singapore, 189352
Singapore

March 17, 2025

Re: K241975
Trade/Device Name: Serv Medical Cdss
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: February 19, 2025
Received: February 19, 2025

Dear Jing Zhang:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

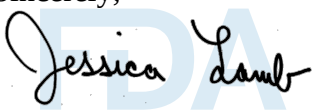
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,



Jessica Lamb
Assistant Director
DHT8B: Division of Radiologic Imaging
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OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241975

Device Name

SERV MEDICAL CDSS

Indications for Use *(Describe)*

SERV MEDICAL CDSS is an image processing software package to be used by trained professionals, including, but not limited to physicians and medical technicians. The software runs on standard “off-the-shelf” hardware and can be used to perform image viewing, processing and analysis of images. Data and images are acquired through DICOM compliant imaging devices. SERV MEDICAL CDSS provides viewing and analysis capabilities for imaging datasets acquired with DSA (Digital Subtraction Angiography).SERV MEDICAL CDSS is not intended for mobile diagnostic use.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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K241975

510(k) Summary

1. Submitter

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JING ZHANG

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the date the summary was prepared: July 1,2024

2. Device

Name of Device: SERV MEDICAL CDSS

Common or Usual Name: Medical Image Management and Processing System

Regulatory Class: II

Product Code: LLZ

Regulation Number: 21 CFR 892.2050

3. Predicate device(s)

Predicate Device: Brainomix 360° e-CTA

Manufacturer: Brainomix Limited

510(k) Number: K192692

Regulatory Class: II

Product Code: LLZ

4. Device description

SERV MEDICAL CDSS is a medical image visualization and processing software package compliant with the DICOM standard and running on an off-the-shelf physical or virtual server.

SERV MEDICAL CDSS allows for the visualization, analysis and post-processing of DICOM compliant DSA images which, when interpreted by a trained physician or medical technician, may

yield information useful in clinical decision making.
SERV MEDICAL CDSS provides a wide range of basic image viewing, processing and manipulation functions, through multiple output formats. The software is used to visualize large vessels from DSA imaging.
SERV MEDICAL CDSS can connect with other DICOM-compliant devices, for example to transfer DSA scans from a Picture Archiving and Communication System (PACS) to SERV MEDICAL CDSS software for processing.

5. Indications for Use

SERV MEDICAL CDSS is an image processing software package to be used by trained professionals, including, but not limited to physicians and medical technicians. The software runs on standard "off-the-shelf" hardware and can be used to perform image viewing, processing and analysis of images. Data and images are acquired through DICOM compliant imaging devices.

SERV MEDICAL CDSS provides viewing and analysis capabilities for imaging datasets acquired with DSA (Digital Subtraction Angiography). SERV MEDICAL CDSS is not intended for mobile diagnostic use.

6. Comparison of Technological Characteristics with the Predicate Device(s)

SERV MEDICAL CDSS has the same intended use and operational characteristics as the predicate devices. Any minor differences between the subject device and the listed predicate devices do no raise any issues of safety or efficacy. Performance data supports that the device is safe and as effective as the predicate device for its intended use.

Therefore, SERV MEDICAL CDSS may be found substantially equivalent to its predicate devices.

SERV MEDICAL CDSS is compared with the following Predicate Devices in terms of intended use, design, material, specifications, and performance:

1) K192692 (Predicate Device), " Brainomix 360° e-CTA ", manufactured by " Brainomix Limited"

Comparison Elements	Subject Device SERV MEDICAL CDSS	Predicate Device (K192692)	Remark
Product code	LLZ	LLZ	SE
Regulation number	21 CFR 892.2050	21 CFR 892.2050	SE
Classification	2	2	SE

Comparison Elements	Subject Device SERV MEDICAL CDSS	Predicate Device (K192692)	Remark
Prescription Use	YES	YES	SE
Indications for use	SERV MEDICAL CDSS is an image processing software package to be used by trained professionals, including, but not limited to physicians and medical technicians. The software runs on standard "off-the-shelf" hardware and can be used to perform image viewing, processing and analysis of images. Data and images are acquired through DICOM compliant imaging devices. SERV MEDICAL CDSS provides viewing and analysis capabilities for imaging datasets acquired with DSA (Digital Subtraction Angiography). SERV MEDICAL CDSS is not intended for mobile diagnostic use.	Brainomix 360° e-CTA is an image processing software package to be used by trained professionals, including, but not limited to physicians and medical technicians. The software runs on standard "off-the-shelf" hardware (physical or virtualized) and can be used to perform image viewing, processing and analysis of images. Data and images are acquired through DICOM compliant imaging devices. Brainomix 360° e-CTA provides viewing and analysis capabilities for imaging datasets acquired with CTA (CT Angiography). Brainomix 360° e-CTA is not intended for mobile diagnostic use.	SE
Environment of use	Clinical/Hospital environment	Clinical/Hospital environment	SE
Target User	Healthcare professionals trained in use of the device	Healthcare professionals trained in use of the device	SE
Energy used and/or delivered	None-software only application. The software application does not deliver or depend on energy delivered to or from patients	None-software only application. The software application does not deliver or depend on energy delivered to or from patients	SE
Supported Modalities for image processing and visualization	DSA	CTA	SE Note 1
PACS functionality	View process and analyze medical images. performs standard PACS functions with respect to querying and listing	View process and analyze medical images. performs standard PACS functions with respect to querying and listing	SE

Comparison Elements	Subject Device SERV MEDICAL CDSS	Predicate Device (K192692)	Remark
DICOM compliance	Yes	Yes	SE
Data acquisition	Acquires medical image data from DICOM compliant imaging devices and modalities	Acquires medical image data from DICOM compliant imaging devices and modalities	SE
Computer Platform	Standard off-the-shelf server or virtual server	Standard off-the-shelf server or virtual server	SE
Materials	N/A – Software only device	N/A – Software only device	SE
Biocompatibility	N/A – Software only device	N/A – Software only device	SE
Sterility	N/A – Software only device	N/A – Software only device	SE
Electrical Safety	N/A – Software only device	N/A – Software only device	SE
Mechanical Safety	N/A – Software only device	N/A – Software only device	SE
Chemical Safety	N/A – Software only device	N/A – Software only device	SE
Thermal Safety	N/A – Software only device	N/A – Software only device	SE
Radiation Safety	N/A – Software only device	N/A – Software only device	SE

Comparison in Detail(s):

Note 1: Supported Modalities for image processing and visualization

DSA and CTA are both CT imaging which is DICOM compliant and the subject device and predicate device would both support Modalities which is DICOM compliant for image processing and visualization. And the software testing results for the subject device has shown that DSA imaging process and visualization function has met the software clinical requirements.

The difference does not raise new concerns of safety and effectiveness for the clinical use.

7. Performance Data

The following performance data are provided in support of the substantial equivalence

determination.

1) Software Verification and Validation

Software documentation consistent with basic documentation level of concern is submitted in this 510(k). System validation testing presented in this 510(k) demonstrated that all software requirement specifications have been met and all software hazards have been mitigated to acceptable risk levels.

2)Summary

Based on the above performance as documented in this application, SERV MEDICAL CDSS is found to have a safety and effectiveness profile that is similar to the predicate device.

8. Conclusions

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the comparison of intended use, design, and performance, SERV MEDICAL CDSS is to be concluded substantial equivalent to its predicate devices.